

# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

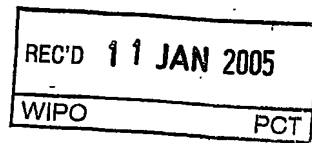
(PCT Rule 44bis)

Applicant's or agent's file reference DAAS13750760	<b>FOR FURTHER ACTION</b>		See item 4 below
International application No. PCT/AU2004/001453	International filing date ( <i>day/month/year</i> ) 22 October 2004 (22.10.2004)	Priority date ( <i>day/month/year</i> ) 22 October 2003 (22.10.2003)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant AMBRI LIMITED			

<p>1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 <i>bis</i>.1(a).</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p>In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.</p>																
<p>3. This report contains indications relating to the following items:</p> <table> <tr> <td><input checked="" type="checkbox"/> Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td><input type="checkbox"/> Box No. II</td> <td>Priority</td> </tr> <tr> <td><input type="checkbox"/> Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input type="checkbox"/> Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/> Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input type="checkbox"/> Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/> Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input checked="" type="checkbox"/> Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table> <p>4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).</p>	<input checked="" type="checkbox"/> Box No. I	Basis of the report	<input type="checkbox"/> Box No. II	Priority	<input type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/> Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/> Box No. VI	Certain documents cited	<input type="checkbox"/> Box No. VII	Certain defects in the international application	<input checked="" type="checkbox"/> Box No. VIII	Certain observations on the international application
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<input checked="" type="checkbox"/> Box No. VIII	Certain observations on the international application															

<p>The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland</p> <p>Facsimile No. +41 22 740 14 35</p>	<p>Date of issuance of this report 24 April 2006 (24.04.2006)</p>
	<p>Authorized officer</p> <p>Dorothee Mülhausen</p> <p>Telephone No. +41 22 338 87 40</p>

# PATENT COOPERATION TREATY



From the:  
INTERNATIONAL SEARCHING AUTHORITY

To:

Blake Dawson Waldron  
Level 39  
101 Collins Street  
MELBOURNE VIC 3000

## PCT

### WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference 13750760		Date of mailing (day/month/year) <b>06 JAN 2005</b>	
<b>FOR FURTHER ACTION</b> See paragraph 2 below			
International application No. <b>PCT/AU2004/001453</b>	International filing date (day/month/year) <b>22 October 2004</b>	Priority date (day/month/year) <b>22 October 2003</b>	
International Patent Classification (IPC) or both national classification and IPC <b>Int. Cl. <sup>7</sup> G01N 27/327, 33/544</b>			
Applicant <b>AMBRI LIMITED et al</b>			

**1. This opinion contains indications relating to the following items:**

- |                                     |              |  |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I    | Basis of the opinion   |
| <input type="checkbox"/>            | Box No. II   | Priority   |
| <input type="checkbox"/>            | Box No. III  | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability   |
| <input type="checkbox"/>            | Box No. IV   | Lack of unity of invention   |
| <input checked="" type="checkbox"/> | Box No. V    | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/>            | Box No. VI   | Certain documents cited  |
| <input type="checkbox"/>            | Box No. VII  | Certain defects in the international application   |
| <input checked="" type="checkbox"/> | Box No. VIII | Certain observations on the international application  |

**2. FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

**3. For further details, see notes to Form PCT/ISA/220.**

Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer <b>ROSS OSBORNE</b> Telephone No. (02) 6283 2404
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**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

**PCT/AU2004/001453**

**Box No. I      Basis of the opinion**

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.  
☐ This opinion has been established on the basis of a translation from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material  
☐ a sequence listing  
☐ table(s) related to the sequence listing
  - b. format of material  
☐ in written format  
☐ in computer readable form
  - c. time of filing/furnishing  
☐ contained in the international application as filed.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

**PCT/AU2004/001453**

**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Claims 1-60	YES
	Claims	NO
Inventive step (IS)	Claims	YES
	Claims 1-60	NO
Industrial applicability (IA)	Claims 1-60	YES
	Claims	NO

**2. Citations and explanations:**

D1 - WO 1997/001092

D2 - WO 1994/007593

D3 - WO 1998/055854

D4 - US 5111221

**NOVELTY (N) Claims 1-60**

The closest prior art are documents D1-D4. D1-D3 are examples of the applicant's prior work in this field.

None of the citations discloses devices or methods of preparing them with all the features claimed.

D1 discloses biosensors which feature a well in a substrate that has a first base layer that can be gold, linker lipids with a hydrophilic sequence, and a hydrophobic region, but the lipids do not appear to be layers within the meaning of the current claims. D2 discloses linker lipids for use in such an arrangement. D2 also discloses, in the examples, a well arrangement for the biosensor coated with adsorbed hydrophobic layers and the use of streptavidin and biotin in layers adsorbed onto gold electrodes. However these layers do not have all the features of the claimed device. D3 discloses an electrode with a base layer to which is attached a 'passivating' layer that contains a hydrophobic region and a hydrophilic head group. The electrode is associated with a 'containment vessel', see example 1, which would seem to equate to a well. However even presuming the passivating layer could be considered equivalent to first and second layer, it does not appear to be attached so that a well extends through it. In addition, while the passivating layer is described as improving the stability of the membrane, there is no indication that the stability is achieved, in part, by preventing disruption of the membrane by air.

D4 discloses what could be considered a well in a base layer that extends through a layer of hydrophilic silica. However no hydrophobic layer appears to be present in the final product and no benefits associated with the well design in preventing disruption of the membrane by air are indicated.

**INVENTIVE STEP (IS) Claims 1-60**

D1 considers the problem of air disruption of membranes but uses a different solution of applying a drying agent to reduce disruption. It is considered that the prior art documents taken alone or in combination do not suggest the solution of a well extending through hydrophobic and hydrophilic layers as claimed for the current device. However as currently drafted, the claims do not require the well to have such dimensions as to retain the bead of liquid which prevents air disruption to the membrane. Without this property the coated devices of the current application are simply variations of the coated sensors of the prior art. For these reasons claims 1-60 lack an inventive step over any one of D1-D4.

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

**PCT/AU2004/001453**

**Box No. VIII      Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The description only supports a 'device' that is a lipid membrane-based biosensor and the claims should be more clearly restricted to such a device. The dimensions of the well need to be defined in accordance with the description such that a bead of polar liquid is retained by the well so as to prevent contact of the membrane with air while allowing rapid exchange with analyte or washing solutions. This appears to be a critical feature of the invention and to the extent that the claims cover arrangements that do not meet these requirements they are not supported by the description.